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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,315	04/12/2004	Bryan Leasure	1001.1749101	2606
28075	7590	11/14/2005	EXAMINER	
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			ROSENZWEIG, JASON	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/822,315	<b>Applicant(s)</b> LEASURE, BRYAN	
	<b>Examiner</b> Jason E. Rosenzweig	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 11-16 and 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 17-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07082004,08122005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Claims 1-10, 17-26 in the reply filed on 10/10/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Palmer (US 6,638,294) et al.
3. Regarding claim 1, Palmer discloses: A medical device, comprising a blood-impermeable wall (Fig 3, Element 66; Approximately Col 4, Ln. 30) defining a cavity

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having a lumen through the wall at a first end opposite a second end (Fig 3), the wall including a flexible section; a frame (Fig 3, Element 40) attached to the wall; and an actuation system attached to the frame for moving the frame between an expanded position and a contracted position (Col 3, Ln. 66).

4. Regarding Claims 8-10, Palmer significant discloses the medical device of claim 1, including a cavity having a slightly flattened conical shape (Fig 3, Element 66) wherein a cross-section of the cavity at the first end is larger than a cross-section of the cavity at the second end when the frame is in the expanded position (Fig 3).

5. Claims 18-20, and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Schiff (US 4,522,195).

6. Regarding claim 18, Schiff discloses: An intravascular pump comprising: a flexible wall defining a pumping chamber (Figure 14, Element 202; Col 13, Line 45) and a pumping mechanism (Figure 14, Element 200) including a frame attached to the wall (Figure 10).

7. Regarding claim 19, Schiff discloses: The pump of claim 18, wherein the pumping mechanism includes a central shaft (Figure 12, Element 114a; Col 11, Line 29) and the frame, Schiff also discloses stiffeners (Fig 3, Elements 28 and 29; Col. 8, Ln 42) which are analogous to struts as a support and structure member.

8. Regarding claim 20, Schiff discloses the pump of claim 19, wherein the pumping mechanism includes a balloon (Fig 3a, Element 20; Col 7, Ln 4).

9. Regarding claim 24 and 25, Schiff discloses the pump of claim 19, further comprising a control system (See abstract; Col 5, Ln. 48) for controlling the pump

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wherein the control system comprises a sensor for measuring heart activity, which is comprises a electrogram signal which is coupled to the controller by a 3-wire lead (See abstract; Col. 5, Ln. 48)

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer in view of Breznock (US 6638253).

13. Regarding claims 3 and 5, Palmer discloses the medical device of claim 2, however he does not specify an actuation system wherein the struts are electrically connected to a voltage source. Breznock teaches a medical device with an actuator (Col 3, Line 39) comprising of electrical leads, a power source, a compressible substrate, and shape memory materials such as Nitinol wherein said bending and controlling of actuation is accomplished with an electrical current (Col 12, Line 20). It

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would be obvious to modify Palmer's device so it could be electrically activated by adding a current source to the struts comprised of an electroactive polymer such as Nitinol.

14. Claims 21-23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff in view of Breznock.

15. Regarding claims 21-23, Schiff discloses: a substantially similar intravascular pump including a memory material (Col 7, Line 26) however does not mention a means for moving a shape memory alloy through its transformation temperature. Breznock specifically discloses a medical device, which utilizes shape memory material, specifically Nitinol (Col 3, Line 42) and uses an electrical current to move the shape memory alloy through a transformation temperature, which allows the material to be used as an actuation device. Brezno discloses the use of a shape memory alloy however does not mention the use of an Electroactive polymer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a Shape memory alloy (SMA) for a Electroactive Polymer (EAP), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

16. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer in view of Bonutti (US 5163949).

17. Regarding claim 4, Palmer significantly discloses the medical device of claim 1, however does not teach the use of a balloon as an actuation system. It would have

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been an obvious matter of design choice to use a balloon to actuate a actuation system comprised of struts as disclosed by Bonutti (Fig 18 and 18A), since applicant has not disclosed any criticality as to exactly how the blood-impermeable wall is opened up. Since applicant has not disclosed as to how a actuation system comprising a balloon and a inflation lumen fluidly attached to the balloon solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with a shape memory such as Nitinol moved through a transformation temperature. The examiner also takes official notice that it would be obvious in the medical device art to modify a device using a shape memory alloy as a actuation system and use a balloon to expand strut-like elements as disclosed by Bonutti.

18. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff in view of Choy (US 4771765).

19. Regarding claim 26, Schiff significantly discloses the medical device of claim 24, however does not mention the use of pacer control of pumps. Choy discloses a medical device specifically a heart assist device and method of use, which teaches the use of a control system, which includes an interface for use with a pacemaker (Figure 25). It would be obvious to one of ordinary skill in the art to modify Schiff's left heart assist device to include a control system to interface with a pacemaker.

20. Claims 2, 6-7, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer (US 6,638,294) et al.

21. Regarding claim 2, Palmer discloses the medical device of claim 1, wherein the actuation system (Fig. 3, Element 24) is made of Nitinol. Nitinol is a shape memory

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material and has been used in various medical devices due to both its shape memory property along with its transformation temperature. A common use of Nitinol is in orthodontic wire where body heat is able to move the shape memory material through its transformation temperature. The Palmer reference teaches a medical device which can self-expand, or be made to expand. Official notice is taken that shape memory materials can be actuated with heating means. It would be obvious to one of ordinary skill in the art to use a shape memory material and a heating means to move a shape memory material through its transformation temperature in order to, for example in this case, utilize a small incision to implant the medical device and allow heating means to move the shape memory material through its transformation temperature.

22. Regarding claims 6-7, Palmer discloses: A medical device of claim 1, however he does not specify the volume of the cavity (Fig 3, Element 66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the size or volume of the cavity in the medical device, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

23. Regarding claim 17, Palmer discloses medical device as described in claim 1 geared towards the circulatory system, Palmer does not specifically mention the use of antithrombotic agents but his device is geared towards removing these agents from the circulatory system. The examiner takes official notice that many devices introduced into the vasculature utilize antithrombotic agents in order to prevent thrombosis in the vasculature where a medical device is placed. It would be obvious to one of ordinary

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skill in the art to introduce an anti-clotting agent to a medical device introduced into the circulatory system to prevent the formation of clots resulting in improved efficacy of the medical device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason E. Rosenzweig whose telephone number is (571)272-5559. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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